

REMARKS

Summary of Office Action

As an initial matter, Applicants note with appreciation that the Examiner has indicated consideration of the Information Disclosure Statements filed April 13 and August 30, 2004 and June 27, 2005 by returning signed and (partially) initialed copies of the Forms PTO-1449 submitted therein. In this regard, Applicants note that on Form PTO-1449 filed August 30, 2004 the Examiner has failed to initial Cite No. 14, i.e., DE 100 02 725. Accordingly, the Examiner is respectfully requested to return another Form PTO-1449 which has Cite No. 14 initialed with the next communication from the Patent and Trademark Office.

Applicants further note with appreciation that the Examiner has acknowledged the claim for foreign priority under 35 U.S.C. § 119(a)-(d) of (f). Certified copies of the priority documents will be submitted in due course.

The Election and Restriction Requirements are made final and claims 3, 4 and 12-55 are withdrawn from consideration, leaving only claims 1, 2 and 5-11 for examination on the merits.

The specification is objected to.

Claims 1, 2 and 5-11 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Harding et al., U.S. Patent No. 5,705,144 (hereafter "HARDING") in view of Schonrock et al., U.S. Patent No. 6,296,857 (hereafter "SCHONROCK").

Claims 1 and 2 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1 and 13 of copending Application No. 11/087,395 and claims 1 and 5 of copending Application No. 11/547,104.

Claims 1 and 2 are also provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1 and 11 of copending Application No. 10/871,819, claims 51 and 67 of copending Application No. 10/871,861 and claims 1, 18 and 20 of copending Application No. 11/157,946, all in view of SCHONROCK.

Response to Office Action

Reconsideration and withdrawal of the objections and rejections of record are respectfully requested in view of the following remarks.

Response to Objection to Specification

The specification is objected to and the Examiner requests that several trademarks mentioned therein be capitalized and be accompanied by the generic terminology.

In response, Applicants respectfully submit that marking the trademarks in the present specification with the “®” symbol should be sufficient to indicate that these marks are protected, and capitalization of the marks should thus, be unnecessary. Also, to the extent known to Applicants the generic terminology of the trademarks mentioned in the specification is already indicated therein.

If the Examiner deems that amendment of the specification is necessary to further denote any information, the Examiner is requested to contact the undersigned to discuss the same.

In view of the foregoing, withdrawal of the objection to the specification is respectfully requested.

Response to Rejection of Claims under 35 U.S.C. § 103(a)

Claims 1, 2 and 5-11 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over HARDING in view of SCHONROCK. The rejection alleges that HARDING teaches a composition for lightening skin which comprises a dioic acid of a general structure which encompasses 8-hexadecene-1,16-dicarboxylic acid and that HARDING further teaches that the composition further contains cosmetic adjuncts such as antioxidants. The rejection concedes that HARDING fails to teach folic acid. In this regard, the rejection relies on SCHONROCK and asserts that this document teaches a method for cosmetically lightening large areas of the skin comprising the antioxidant folic acid. In view thereof, the Examiner essentially takes the position that, absent a showing of unexpected results, it would allegedly have been obvious to one of ordinary skill in the art to incorporate folic acid into the compositions of HARDING. The rejection further asserts that the motivation to combine the compounds of HARDING with the compounds of SCHONROCK arises from the fact that the compositions of these two documents are both used for lightening large areas of the skin.

Applicants respectfully traverse this rejection. Specifically, it is pointed out that while HARDING gives a general structural formula for the saturated and unsaturated dioic acids for use in the compositions described therein, this general formula apparently encompasses more than a hundred individual compounds.

HARDING does mention a number of specific dioic acids which are encompassed by the general formula depicted therein and also discloses several exemplary compositions which comprise one or more specific dioic acids. 8-Hexadecene-1,16-dicarboxylic acid is however, not among the specific dioic acids mentioned in HARDING, let alone employed in any of the various exemplary compositions disclosed therein. In fact, none of the dioic acids, whether saturated or (mono- or di-)

unsaturated, employed in the exemplary compositions of HARDING even contains 16 carbon atoms (as 8-hexadecene-1,16-dicarboxylic acid apparently does).

Further, regarding the antioxidants which may be present in the compositions of HARDING, this document states at column 11, lines 18-30 (emphases added):

Other Cosmetic Adjuncts

Examples of conventional adjuncts which can optionally be employed include preservatives, such as para-hydroxy benzoate esters; antioxidants, such as butylated hydroxytoluene; humectants, such as glycerol, sorbitol, 2-pyrrolidone-5-carboxylic acid, dibutylphthalate, gelatin, polyethylene glycol, such as PEG 200-600; buffers, such as lactic acid together with a base such as triethanolamine or sodium hydroxide; waxes, such as beeswax, ozokerite wax, paraffin wax; plant extracts, such as aloe vera, cornflower, witch hazel, elderflower, cucumber; thickeners; activity enhancers; colourants; and perfumes. Cosmetic adjuncts can form the balance of the composition.

Accordingly, HARDING merely mentions in passing that antioxidants such as butylated hydroxytoluene may, *inter alia*, be optionally present in the compositions described therein. The importance (or better: lack thereof) attached to these optional adjuncts can be taken from the fact that HARDING fails to give concentration ranges for any of these “other” cosmetic adjuncts and that none of the numerous compositions of the Examples of HARDING contains any antioxidant.

It is submitted that in view of the foregoing facts, HARDING fails to provide any motivation or apparent reason for one of ordinary skill in the art to provide a composition which comprises (a) 8-hexadecene-1,16-dicarboxylic acid, i.e., a dioic acid which is not even among the dioic acids which are specifically mentioned in HARDING, let alone is employed in any of the various exemplary compositions thereof, in combination with (b) an antioxidant, i.e., a component which is mentioned in HARDING merely in passing as one of the many optional types of components of the compositions disclosed therein and is not employed in a single exemplary composition of HARDING, either.

Applicants are aware that the present rejection relies on a combination of HARDING and SCHONROCK. However, one of the very few things that SCHONROCK appears to have in common with HARDING is that in both documents antioxidants are identified as merely one of the many optional types of components which may be present in the compositions disclosed therein. Specifically, in col. 12, lines 38-48, SCHONROCK states (emphases added):

The cosmetic and dermatological preparations according to the invention may comprise cosmetically active ingredients, cosmetic auxiliaries and/or cosmetic additives conventionally used in such preparations, for example antioxidants, preservatives, bactericides, fragrances, antifoams, colorants, colour pigments, thickeners, surfactants, emulsifiers, plasticizers, moisturizers and/or humectants, fats, oils, waxes or other customary constituents of a cosmetic or dermatological formulation such as alcohols, polyols, polymers, foam stabilizers, electrolytes, organic solvents or silicone derivatives.

Clearly, the above passage does not convey the impression that it is critical to use a (any) antioxidant in the compositions of SCHONROCK.

At any rate, it is submitted that there is no motivation to combine HARDING and SCHONROCK because these compositions are entirely different with respect to their essential components. Specifically, the compositions of HARDING comprise retinol and one or more dioic acids of the general formula depicted therein as critical components "which together behave synergistically in reducing skin blotchiness and mottling due to hyperpigmentation" (col. 2, lines 52-56 of HARDING).

The critical components of the compositions of SCHONROCK, on the other hand are specific oligopeptides (see, e.g., abstract of SCHONROCK) which "have shown to be outstanding active ingredients against undesired pigmentation, in particular local hyperpigmentation, both preventatively and therapeutically" (col. 10, lines 7-15).

Further, even if one were to assume, *arguendo*, that one of ordinary skill in the art would

combine HARDING and SCHONROCK for the sole reason that these two documents disclose compositions which may be used for similar purposes, it is not seen why this combination would provide an apparent reason for one of ordinary skill in the art to use an antioxidant (and in particular, folic acid, i.e., one of the many exemplary antioxidants which are mentioned but whose use in a composition is not exemplified in SCHONROCK) in a composition of HARDING which further comprises 8-hexadecene-1,16-dicarboxylic acid.

In this regard, it is to be particularly taken into account that in none of the compositions of HARDING and SCHONROCK do antioxidants play any role, let alone any role for the intended purpose of these compositions, e.g., a lightening of skin onto which these compositions are applied. In other words, it is apparent from the disclosures of HARDING and SCHONROCK that incorporating an antioxidant in the compositions disclosed therein will not significantly change the properties of these compositions, let alone the skin-lightening effect thereof. In fact, if anything at all, SCHONROCK even reinforces the impression conveyed by HARDING, i.e., that the use of an antioxidant in the compositions disclosed therein is not associated with any particular advantage, let alone with an advantage with respect to the skin-lightening effect of these compositions.

Regarding present claims 9 to 11 (which recite concentration ranges of 8-hexadecene-1,16-dicarboxylic acid in the claimed compositions) it is additionally pointed out that while HARDING does disclose general concentration ranges of dioic acid(s) which (slightly) overlap the concentration ranges recited in claims 9 to 11, it is to be pointed out that the concentration of the dioic acid(s) in the compositions of the various Examples of HARDING is at least 15 % by weight and is in most cases 20 % by weight, i.e., significantly higher than the upper values of the concentration ranges which are recited in present claims 9-11. (In this regard, it is noted that the highest concentration of 8-hexadecene-1,16-dicarboxylic acid which is used in the numerous exemplary compositions shown

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in the present specification is 1.00 % by weight). This is yet another reason why HARDING is unable to render obvious the subject matter of present claims 9-11.

Applicants submit that for at least all of the foregoing reasons, the rejection of claims 1, 2 and 5-11 under 35 U.S.C. § 103(a) over HARDING in view of SCHONROCK is unwarranted and should thus be withdrawn, which action is respectfully requested.

Response to Provisional Rejection of Claims

The provisional rejections of claims 1 and 2 on the ground of nonstatutory obviousness-type double patenting over claims of several co-pending applications are noted. In this regard, Applicants respectfully request that these rejections be held in abeyance until the Examiner has indicated allowable subject matter. Applicants will then decide whether the filing of one or more terminal disclaimers is appropriate.

CONCLUSION

In view of the foregoing, it is believed that all of the claims in this application are in condition for allowance (with the possible exception of obviousness-type double patenting issues), and a confirmation to this effect is respectfully requested. If any issues yet remain which can be resolved by a telephone conference, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Respectfully submitted,
Jan BATZER et al.

A handwritten signature in black ink, appearing to read "Neil F. Greenblum", written over a horizontal dashed line.

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